Amendments to the Claims

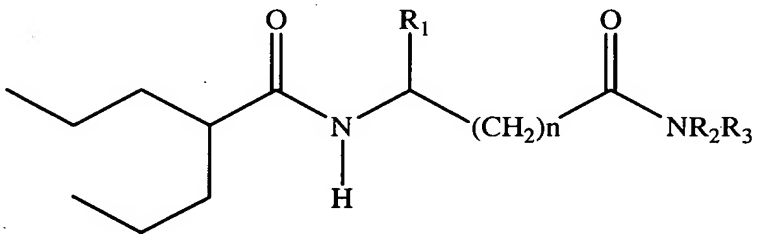
Please cancel claims 30-37, 77-81, 93-107 and 120 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in this or a related application.

Please amend claims 3, 5, 7-9, 12, 16, 20, 57-65, 112 and 119 under the provisions of 37 C.F.R. §1.121, as set forth in the Federal Register on June 30, 2003 as follows:

1. (Original) A sustained release solid dosage form comprising the following components:

a) a uniform admixture of:

(i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:



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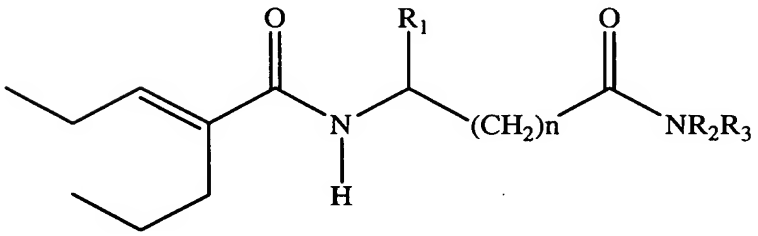


wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

(ii) a binder; and

b) a hydroxypropylmethyl cellulose.

2. (Original) The solid dosage form of claim 1, wherein the solid dosage form is a tablet.

3. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, wherein the uniform admixture of component a) further comprises a filler.

4. (Original) The solid dosage form of claim 3, wherein the filler comprises a microcrystalline cellulose.

5. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, wherein the hydroxypropylmethyl cellulose comprises 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxyproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve, has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C, and has a pH in the range 5.5-8.0.

6. (Original) The solid dosage form of claim 5, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

7. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, further comprising as additional components a filler, a lubricant and a flow agent.

8. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, wherein the binder of component a)(ii) comprises hydroxypropyl cellulose.

9. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, further comprising a different hydroxypropylmethyl cellulose as a component.

10. (Original) The solid dosage form of claim 3, further comprising as additional components a filler, a lubricant and a flow agent.

11. (Original) The solid dosage form of claim 10, further comprising a different hydroxypropylmethyl cellulose as a component.

12. (Currently Amended) The solid dosage form of claim 9 ~~or 11~~, wherein the different hydroxypropylmethyl cellulose comprises 19-24% by weight methoxyl substituent, 7-9% by weight hydroxypropoxyl substituent, has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C, has a pH in the range 5.5-8.0 and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

13. (Original) The solid dosage form of claim 12, wherein at least 90% of the hydroxypropylmethyl

cellulose passes through a No. 100 US standard sieve.

14. (Original) The solid dosage form of claim 7, wherein

the filler comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose, methylcellulose, carboxymethylcellulose, calcium carbonate, calcium sulfate kaolin, sodium chloride, powdered cellulose, sucrose, mannitol or a combination of two or more of the foregoing;

the lubricant comprises magnesium stearate, sodium stearyl fumarate, hydrogenated castor oil, hydrogenated soybean oil, polyethylene glycol or a combination of two or more of the foregoing; and

the flow agent comprises a colloidal fumed silica, or colloidal silicon dioxide.

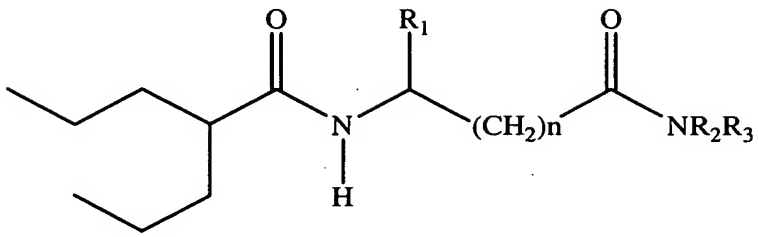
15. (Original) The solid dosage form of claim 14 wherein

the filler comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

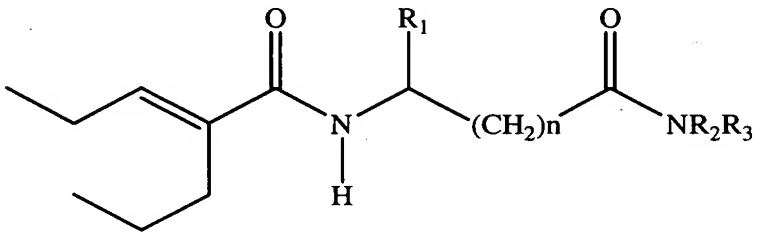
the lubricant comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

the flow agent comprises a colloidal fumed silica.

16. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~ wherein the active ingredient is a compound having the structure:



or



wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

17. (Original) The solid dosage form of claim 16, wherein the active ingredient is N-(2-Propylpentanoyl)glycinamide.

18. (Original) A sustained release solid dosage form comprising the following components:

a) a uniform admixture of:

(i) N-(2-Propylpentanoyl)glycinamide; and

(ii) a binder;

b) a hydroxypropylmethyl cellulose; and

c) a different hydroxypropylmethyl cellulose.

19. (Original) The solid dosage form of claim 18, wherein the solid dosage form is a tablet.

20. (Currently Amended) The solid dosage form of claim 18 ~~or 19~~, comprising a filler, a lubricant and a flow agent as additional components and wherein the uniform admixture of component a) further comprises a filler.

21. (Original) The solid dosage form of claim 20, wherein

the binder of component a)(ii) comprises hydroxypropyl cellulose;

the filler of component a) comprises a microcrystalline cellulose;

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C;

the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C;

the filler component comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

the lubricant component comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

the flow agent component comprises a colloidal fumed silica.

22. (Original) The solid dosage form of claim 21, comprising the following components:

a) a uniform admixture of:

(i) from 50 mg/solid dosage form to 1000 mg/solid dosage form of N-(2-propylpentanoyl) glycinamide,

(ii) from 1 mg/solid dosage form to 100 mg/solid dosage form hydroxypropyl cellulose; and

(iii) from 1 mg/solid dosage form to 200 mg/solid dosage form microcrystalline cellulose;

b) from 10 mg/solid dosage form to 300 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

c) from 10 mg/solid dosage form to 300 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

d) from 1 mg/solid dosage form to 300 mg/solid dosage form microcrystalline cellulose, anhydrous

dicalcium phosphate, lactose or a combination of two or more of the foregoing;

e) from 0.1 mg/solid dosage form to 20 mg/solid dosage form of magnesium stearate, sodium stearyl fumarate or a combination thereof; and

f) from 0.1 mg/solid dosage form to 15 mg/solid dosage form a colloidal fumed silica.

23. (Original) The solid dosage form of claim 21, comprising the following components:

a) a uniform admixture of:

(i) from 500 mg/solid dosage form to 850 mg/solid dosage form of N-(2-propylpentanoyl) glycinamide,

(ii) from 25 mg/solid dosage form to 75 mg/solid dosage form hydroxypropyl cellulose; and

(iii) from 50 mg/solid dosage form to 150 mg/solid dosage form microcrystalline cellulose;

b) from 100 mg/solid dosage form to 300 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

c) from 20 mg/solid dosage form to 150 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% hydroxylproproxyl substituent and has a particle size distribution such that at

least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

d) from 20 mg/solid dosage form to 100 mg/solid dosage form microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

e) from 2 mg/solid dosage form to 20 mg/solid dosage form of magnesium stearate, sodium stearyl fumarate or a combination thereof; and

f) from .5 mg/solid dosage form to 5 mg/solid dosage form a colloidal fumed silica,

per 1 gram solid dosage form.

24. The solid dosage form of ~~any one of claims 22 or 23~~ claim 23, wherein at least 90% of the hydroxypropylmethyl cellulose of component b), of component c), or of both component b) and c) passes through a No. 100 US standard sieve.

25. (Original) The solid dosage form of claim 23, wherein

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C; and

the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

26. (Original) The solid dosage form of claim 23, comprising the following components:

a) a uniform admixture of :

(i) 500 mg/solid dosage form N-(2-Propylpentanoyl)glycinamide,

(ii) 50 mg/solid dosage form hydroxypropyl cellulose; and

(iii) 100 mg/solid dosage form microcrystalline cellulose;

b) 150 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

c) 60 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

d) 20 mg/solid dosage form lactose;

e) 4.5 mg/solid dosage form magnesium stearate; and

f) 1 mg/solid dosage form colloidal fumed silica.

27. (Original) The solid dosage form of claim 26, wherein at least 90% of the hydroxypropylmethyl cellulose of component b), of component c), or of

both component b) and c) passes through a No. 100 US standard sieve.

28. (Original) The solid dosage form of claim 26, wherein

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C; and

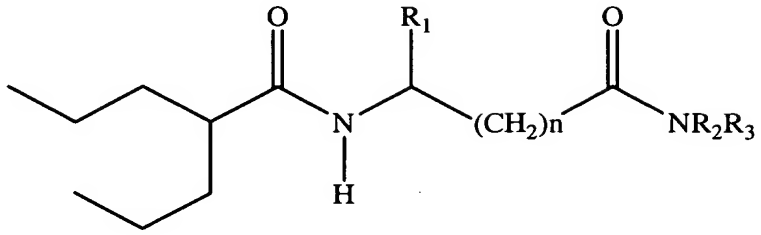
the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

29. (Original) A hard compressed tablet comprising a uniform admixture of the following components:
a) N-(2-Propylpentanoyl)glycinamide;
b) a hydroxypropylmethyl cellulose; and
c) a different hydroxypropylmethyl cellulose.

Claims 30-37. (Canceled)

38. (Original) A composition in granulate form comprising a uniform admixture of:

(i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:



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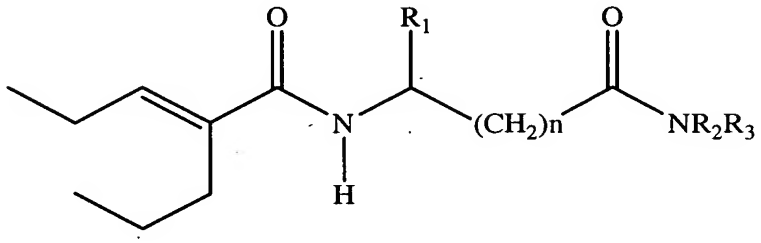
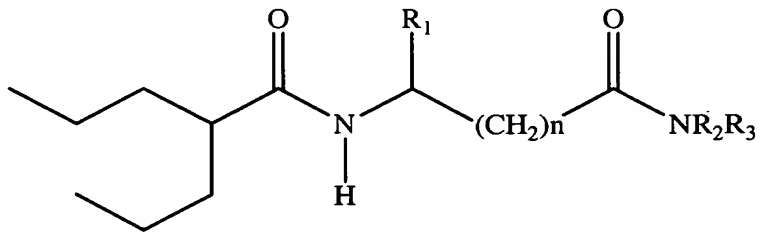


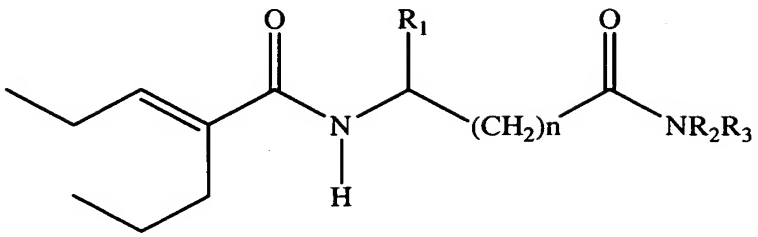
wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

(ii) a hydroxypropyl cellulose.

39. (Original) The composition of claim 38, wherein the active ingredient comprises a compound having the structure:



or



wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

40. (Original) The composition of claim 38, wherein the active ingredient comprises valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium or valpromide.

41. (Original) A tablet comprising the granulate of claim 38 as a component.

42. (Original) The tablet of claim 41, wherein the granulate further comprises a filler.

43. (Original) The tablet of claim 41, further comprising a hydroxypropylmethyl cellulose as a component.

44. (Original) The tablet of claim 41, further comprising as additional components a filler, a lubricant and a flow agent.

45. (Original) The tablet of claim 43, further comprising as additional components a filler, a lubricant and a flow agent.

46. (Original) The tablet of claim 43, further comprising a different hydroxypropylmethyl cellulose as a component.

47. (Original) The tablet of claim 43, wherein

the hydroxypropylmethyl cellulose has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

48. (Original) The tablet of claim 47, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

49. (Original) The tablet of claim 47, wherein

the hydroxypropylmethyl cellulose has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C.

50. (Original) The tablet of claim 46, wherein

the different hydroxypropylmethyl cellulose has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of

the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

51. (Original) The tablet of claim 50, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

52. (Original) The tablet of claim 50, wherein

the different hydroxypropylmethyl cellulose has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

53. (Original) The tablet of claim 42, wherein the filler in the granulate is a microcrystalline cellulose.

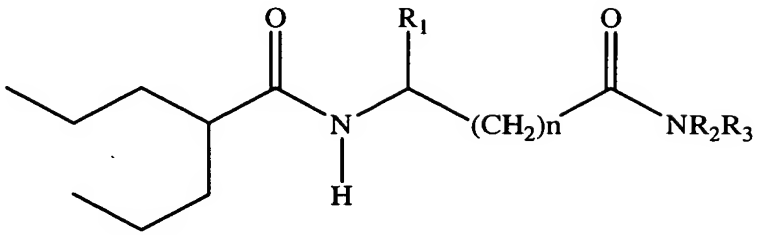
54. (Original) The tablet of claim 45, wherein

the filler comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

the lubricant comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

the flow agent comprises a colloidal fumed silica.

55. (Original) A sustained release tablet comprising a compound having the structure:



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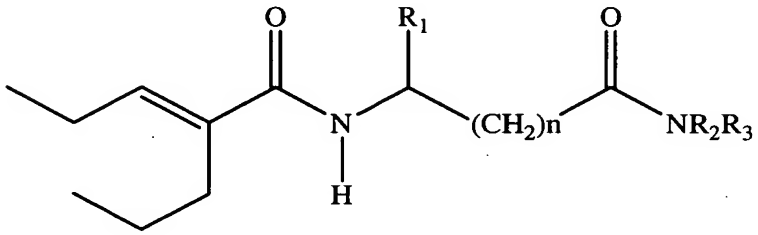


wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

56. (Original) The sustained release tablet of claim 55, wherein the compound is N-(2-propylpentanoyl)glycinamide.

57. (Currently Amended) A method of treating neuropathic pain in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby treat the neuropathic pain in the subject.

58. (Currently Amended) A method of treating a headache disorder in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby treat the headache disorder in the subject.

59. (Currently Amended) A method of treating epilepsy in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby treat epilepsy in the subject.

60. (Currently Amended) A method of controlling seizures in a subject suffering from epilepsy comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby control the seizures in the subject.

61. (Currently Amended) A method of treating pain in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby treat pain in the subject.

62. (Currently Amended) A method of pain prophylaxis in a subject in need of such treatment comprising administering to the subject a prophylactic dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby effect pain prophylaxis in the subject.

63. (Currently Amended) A method of treating mania in bipolar disorder in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby treat mania in bipolar disorder in the subject.

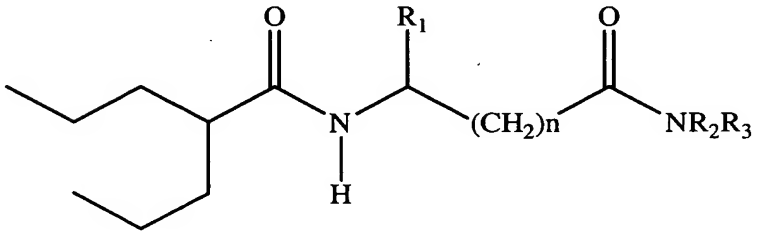
64. (Currently Amended) A method of attenuating bipolar mood swings in a subject suffering from bipolar disorder comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-28 or the tablet of any one of claims 29-37 or 41-56~~ claim 1 in order to thereby attenuate the bipolar mood swings in the subject.

65. (Currently Amended) A process for preparing the solid dosage form of claim 1 ~~or 2~~, comprising the steps of:

a) admixing predetermined amounts of

(i) an active ingredient selected from the group consisting of valproic sodium acid,

a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:



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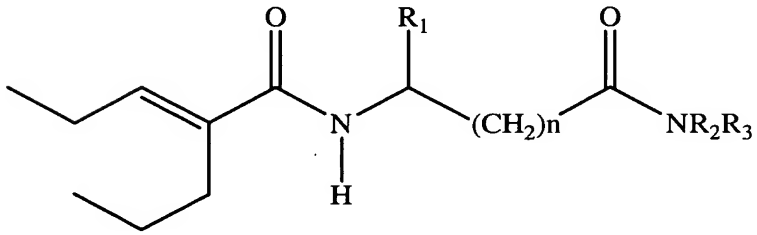


wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

(ii) a binder;

b) admixing the uniform mixture of step a) with a predetermined amount of a hydroxypropylmethyl cellulose; and

c) compressing the mixture of step b) to form the tablet.

66. (Original) The process of claim 65, wherein step b) further comprises admixing the uniform mixture with

a predetermined amount of a different hydroxypropylmethyl cellulose.

67. (Original) The process of claim 66, wherein step b) further comprises admixing the uniform mixture with predetermined amounts of a filler, a lubricant and a flow agent.

68. (Original) The process of claim 67, wherein the flow agent comprises colloidal fumed silica.

69. (Original) The process of claim 67, wherein the filler comprises microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing.

70. (Original) The process of claim 69, wherein the filler comprises lactose.

71. (Original) The process of claim 67, wherein the lubricant comprises magnesium stearate or sodium stearyl fumarate or a combination thereof.

72. (Original) The process of claim 71, wherein the lubricant comprises magnesium stearate.

73. (Original) The process of claim 66, wherein each hydroxypropylmethyl cellulose of step b) has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of

the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

74. (Original) The process of claim 73, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

75. (Original) The process of claim 73, wherein

the first hydroxypropylmethyl cellulose has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C; and

the second hydroxypropylmethyl cellulose has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

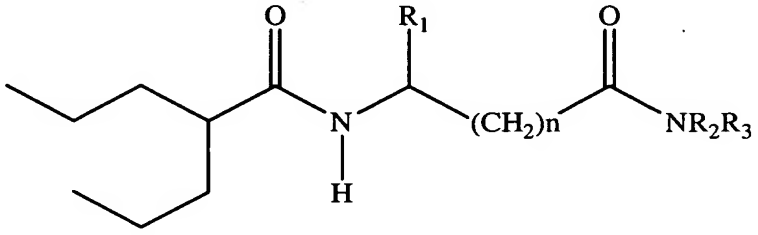
76. (Original) A process for preparing the hard compressed tablet of claim 29 comprising the steps of:

a) admixing predetermined amounts of N-(2-Propylpentanoyl)glycinamide, hydroxypropylmethyl cellulose, and a different hydroxypropylmethyl cellulose; and

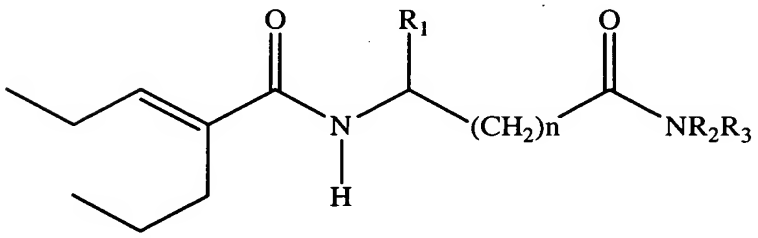
b) compressing the mixture of step a) to form the hard compressed tablet.

Claims 77-81. (Canceled)

82. (Original) A process for preparing the composition in granulate form of claim 38, comprising granulating a predetermined amount of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide or a compound having the structure:



or



wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3, and a predetermined amount of hydroxypropyl cellulose to form the composition in granulate form.

83. (Original) A process for preparing a sustained release tablet comprising the steps of:

a) admixing the granules of claim 38 with predetermined amounts of a hydroxypropylmethyl cellulose; and

b) compressing the mixture of step a) to form the tablet.

84. (Original) The process of claim 83, wherein step a) further comprises admixing the granules with a predetermined amount of each of a different hydroxypropylmethyl cellulose, a filler, a lubricant and a flow agent.

85. (Original) The process of claim 84, wherein the flow agent comprises colloidal fumed silica.

86. (Original) The process of claim 84, wherein the filler comprises microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing.

87. (Original) The process of claim 86, wherein the filler is lactose.

88. (Original) The process of claim 84, wherein the lubricant comprises magnesium stearate or sodium stearyl fumarate or a combination thereof.

89. (Original) The process of claim 88, wherein the lubricant comprises magnesium stearate.

90. (Original) The process of claim 83, comprising the steps of:

a) admixing the granules with predetermined amounts of hydroxypropyl methyl cellulose having an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C, and hydroxypropyl methyl cellulose having an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C; and

b) compressing the mixture of step a) to form the tablet.

91. (Original) The process of claim 90, wherein step a) further comprises admixing the granules with predetermined amounts of a flow agent, a filler, and a lubricant.

92. (Original) The process of claim 91 comprising the steps of

a) admixing the granules with

a predetermined amount of hydroxypropylmethyl cellulose with an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C which results in tablets containing 150 mg/tablet;

a predetermined amount of hydroxypropyl methyl cellulose with an apparent viscosity of 6,138-9,030 millipascal-seconds

(nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C which results in tablets containing 60 mg/tablet;

a predetermined amount of lactose which results in tablets containing 20 mg/tablet;

a predetermined amount of magnesium stearate which results in tablets containing 4.5 mg/tablet; and

a predetermined amount of a colloidal fumed silica which results in tablets containing 1 mg/tablet; and

b) compressing the mixture of step a) to form the tablet.

Claims 93-107. (Canceled)

108. (Original) A controlled release oral unit dose composition comprising N-(2-propylpentanoyl) glycinamide and at least one pharmaceutically acceptable carrier, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycinamide between 4 and 24 hours after ingestion of a single oral unit dose.

109. (Original) The controlled release oral unit dose composition of claim 108, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)

glycinamide between 4 and 12 hours after ingestion of a single oral unit dose.

110. (Original) The controlled release oral unit dose composition of claim 109, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycinamide between 6 and 12 hours after ingestion of a single oral unit dose.

111. (Original) The controlled release oral unit dose composition of claim 110, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycinamide between 6 and 8 hours after ingestion of a single oral unit dose.

112. (Currently Amended) The controlled release oral dose composition of ~~any one of claims 108 to 111~~ claim 108, wherein the peak blood plasma level of N-(2-propylpentanoyl) glycinamide is from 0.5 micrograms/ml to 16 micrograms/ml per a 1000 mg dose of N-(2-propylpentanoyl) glycinamide in the composition.

113. (Original) The controlled release oral dose composition of claim 108, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycine in the human subject from 0.5 µg/mL to 1.7 µg/mL per a 1000 mg dose of N-(2-propylpentanoyl) glycinamide in the composition.

114. (Original) A controlled release oral dose composition comprising N-(2-propylpentanoyl) glycinamide and a pharmaceutically acceptable carrier, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycinamide of 0.5 µg/mL to 16 µg/mL per a 1000 mg dose in the composition.

115. (Original) A controlled release oral dose composition comprising N-(2-propylpentanoyl) glycinamide and a pharmaceutically acceptable carrier, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl) glycine of 0.5 µg/mL to 1.7 µg/mL per a 1000 mg dose of N-(2-propylpentanoyl) glycinamide in the composition.

116. (Original) A method of inducing in a human subject a peak blood plasma level of N-(2-propylpentanoyl) glycinamide between 4 and 24 hours after administration of N-(2-propylpentanoyl) glycinamide, comprising administering to the human subject a controlled release oral unit dose composition comprising N-(2-propylpentanoyl) glycinamide and at least one pharmaceutically acceptable carrier, which composition induces a peak blood plasma level of N-(2-propylpentanoyl) glycinamide between 4 and 24 hours after administration of a single oral unit dose.

117. (Original) The method of claim 116, wherein the peak blood plasma level of N-(2-propylpentanoyl) glycinamide occurs between 4 and 12 hours after administration.

118. (Original) The method of claim 116, wherein the peak blood plasma level of N-(2-propylpentanoyl) glycinamide is 0.5 µg/mL to 16 µg/mL per 1000 mg dose of N-(2-propylpentanoyl) glycinamide in the composition.

119. (Currently Amended) The method of ~~any one of claims 116-118~~ claim 116, wherein the administration to the human subject of a controlled release oral unit dose composition comprising N-(2-propylpentanoyl) glycinamide and at least one pharmaceutically acceptable carrier induces a peak blood plasma level of N-(2-propylpentanoyl) glycine in the human subject from 0.5 µg/mL to 1.7 µg/mL upon administration of a single 1000 mg dose of N-(2-propylpentanoyl) glycinamide.

120. (Canceled)